

## **REMARKS**

Claims 15-24 stand pending in the present application. By this Amendment, Applicants have canceled claims 2, 7, 8 and 11-13 and added new claims 15-24. Applicants respectfully submit that the present application is in condition for allowance based on the discussion which follows.

The specification was objected to failing to include an abstract of the disclosure. Applicants wish to use the abstract from the PCT/FR99/02643 application and by this Amendment have enclosed an abstract identical to the one in the PCT application.

The claims were objected to for failing to include an introductory phrase. By this Amendment, Applicants have amended the claims to add the introductory phrase "WHAT IS CLAIMED IS:" thereby obviating the noted objection.

The now canceled claims were rejected under 35 U.S.C. § 101 and in particular claim 2 was rejected for being directed to non-statutory subject matter. By this Amendment, Applicants have canceled the previous claims and rewritten them as new claims 15-24 in which claims 15-22 are directed to an isolated nucleic acid in accordance with the suggested terminology of the Examiner and thereby avoiding a possible 35 U.S.C. § 101 rejection to the new claims. Further, Applicants submit that new claims 23 and 24 which are directed to an expression vector and a host cell transformed with the expression vector as recited in claims 23 and 24 respectively, are directed to statutory subject matter in accordance with 35 U.S.C. § 101.

Claims 12 and 13 were rejected under 35 U.S.C. § 112, first paragraph, which are now moot as a result of Applicants canceling claims 12 and 13.

Claims 2, 7, 8 and 11-13 were rejected under 35 U.S.C. § 112, second paragraph. In particular claim 2 was rejected as being vague for reciting "homologous" and claim 7 was rejected as being vague for using the term "expression cassette". By this Amendment, as noted above claim 2, 7, 8 and 11-13 have been canceled and new claims 15-24 have been added. Applicants submit that new claims 15-24 are not indefinite based on the discussion which follows.

The new claims 15-22 are directed to an isolated nucleic acid encoding a polypeptide specific for pathogenic *Neisseria* strains or an antigenic fragment thereof, the amino acid sequence of said specific polypeptide showing at least 80% identity with the sequence SEQ ID NO: 8, excluding the sequence SEQ ID NO: 74A or 95A. These claims are supported by the present specification, page 4, 2<sup>nd</sup> paragraph, and page 7, 2<sup>nd</sup> paragraph. The polypeptide of sequence SEQ ID NO: 53 corresponds to the amino acids from position 28 to 1067 of the sequence SEQ ID NO: 8. This can be drawn from the specification, page 5, lines 30-34, together with the sequence SEQ ID NO: 8. New claims 23 and 24 correspond to now canceled claims 7 and 8, respectively.

The Examiner alleges that now canceled claim 2 would be vague in the recitation "homologous". The new claims specify a degree of sequence identity, namely, at least 80%. Therefore, the new claims sufficiently describe the degree of homology to render the claims definite.

With regard to the rejection of claim 7 as being vague in the recitation "expression cassette", Applicants respectfully disagree. First, the term "expression cassette" is a standard term ubiquitous in the field of molecular biology. Furthermore, in view of the specification, page 11, lines 27-31 and page 12, lines 11-35, one of ordinary

skill in the art would readily understand the meaning of the term "expression cassette". As to the "Conditions allowing expression", now canceled claim 7 (corresponding to new claim 23) recites that the expression vector is placed under conditions allow expression of the nucleotide sequence. The subject matter basis for claim 23 is fully supported by the present specification as filed on page 11, lines 27-30, that indicates that the polynucleotide is placed under the control of elements allowing its expression. One skilled in the art would readily understand that the "conditions allowing expression" of a nucleotide sequence refer to elements such as promoters, etc.

Based on the foregoing discussion, Applicants respectfully submit that all pending claims are in compliance with 35 U.S.C. § 112, second paragraph.

Claims 2, 7, 8, 12 and 13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hammond et al U.S. Patent No. 5,147,800 (hereinafter "Hammond"). Applicants respectfully submit that added claims 15-24 are not anticipated by Hammond. The present invention as recited by claim 15 is directed to an isolated nucleic acid which encodes a polypeptide specific for pathogenic *Neisseria* strains that comprises an amino acid sequence which exhibits at least 80% identity with the amino acid sequence of SEQ ID NO: 8 or an antigenic fragment thereof provided that the nucleic acid is not SEQ ID NO: 74A or SEQ ID NO: 95A.

Hammond discloses recombinant hosts expressing a gene encoding type II restriction endonucleases NgoAI and NgoAIII and/or modification methylase from *Neisseria gonorrhoeae*.

However, the polypeptide of SEQ ID NO: 8, which is encoded by the nucleic acid according to the present invention, has been described to be an autotransported serine

protease (or AspA). This assertion is supported by the article from Turner et al (2000) describing an AspA from *N. meningitides* strain Z 4181, noting that the AspA contains 1067 amino acids and corresponds to the amino acid sequence SEQ ID NO: 8. A copy of the Turner reference is attached as an Appendix to this Amendment.

Accordingly, the claimed nucleic acids are necessarily distinct from the restriction endonucleases or modification methylase as described by Hammond.

Thus, the subject matter of claims 15-24 is not anticipated by Hammond.

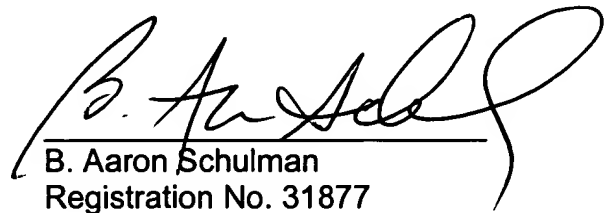
Furthermore, the present invention as currently claimed is not suggested by Hammond and therefore the present invention is not obvious to one of ordinary skill in the art from the disclosure of Hammond. Moreover, Hammond provides no motivation, hint, or guidance to one skilled in the art to carry out the invention.

In view of the foregoing, Applicants respectfully submit that all pending claims are clear of the prior art including Hammond.

In view of the foregoing, Applicants respectfully submit that the present application is in condition for allowance.

Respectfully submitted,

LARSON & TAYLOR, PLC

  
B. Aaron Schulman  
Registration No. 31877

Dated: July 8, 2003

1199 North Fairfax Street, Suite 900  
Alexandria, Virginia 22314  
(703) 739-4900



**ATTACHMENT A**  
**Amendments to the Specification**

Please insert the following new section as provided below.

---

**ABSTRACT**

C<sub>1</sub> The invention concerns nucleic acids coding for polypeptides specific of the *Neisseria* genus pathogenic strains, the corresponding polypeptides, and their diagnostic and therapeutic applications.

---



## ATTACHMENT B Amendments to the Claims

Following herewith is a complete listing of the claims, including a marked copy of the currently amended claims, and the newly added heading.

### WHAT IS CLAIMED IS:

---

1. (Withdrawn)

2. (Canceled)

3-6. (Withdrawn)

7-9. (Canceled)

10. (Withdrawn)

11-13. (Canceled)

14. (Withdrawn)

15. (New) An isolated nucleic acid which encodes (i) a polypeptide specific for pathogenic *Neisseria* strains that comprises an amino acid sequence which exhibits at least 80% identity with the amino acid sequence as shown in SEQ ID NO: 8 or (ii) an antigenic fragment thereof; provided that the nucleic acid sequence is not SEQ ID NO: 74A or SEQ ID NO: 95A.

C<sub>3</sub> 16. (New) The isolated nucleic acid according to claim 15, which encodes (i) a polypeptide specific for pathogenic *Neisseria* strains and comprising an amino acid sequence which exhibits at least 80% identity with the amino acid sequence as shown in SEQ ID NO: 53 or (ii) an antigenic fragment thereof; provided that the nucleic acid sequence is not SEQ ID NO: 74A or SEQ ID NO: 95A.

17. (New) The isolated nucleic acid according to claim 15, which encodes (i) a polypeptide specific for pathogenic *Neisseria* strains and comprising an amino acid sequence which exhibits at least 90% identity with the amino acid sequence as shown in SEQ ID NO: 8 or (ii) an antigenic fragment thereof; provided that the nucleic acid sequence is not SEQ ID NO: 74A or SEQ ID NO: 95A.

18. (New) The isolated nucleic acid according to claim 15, which encodes (i) a polypeptide specific for pathogenic *Neisseria* strains and comprising an amino acid sequence which exhibits at least 90% identity with the amino acid sequence as shown in SEQ ID NO: 53 or (ii) an antigenic fragment thereof; provided that the nucleic acid sequence is not SEQ ID NO: 74A or SEQ ID NO: 95A.

C<sub>3</sub>  
19. (New) The isolated nucleic acid according to claim 15, which encodes (i) a polypeptide specific for pathogenic *Neisseria* strains and comprising an amino acid sequence which exhibits at least 95% identity with the amino acid sequence as shown in SEQ ID NO: 8 or (ii) an antigenic fragment thereof; provided that the nucleic acid sequence is not SEQ ID NO: 74A or SEQ ID NO: 95A.

20. (New) The isolated nucleic acid according to claim 15, which encodes (i) a polypeptide specific for pathogenic *Neisseria* strains and comprising an amino acid sequence which exhibits at least 95% homology with the amino acid sequence as shown in SEQ ID NO: 53 or (ii) an antigenic fragment thereof; provided that the nucleic acid sequence is not SEQ ID NO: 74A or SEQ ID NO: 95A.

21. (New) The isolated nucleic acid according to claim 15, which encodes (i) a polypeptide specific for pathogenic *Neisseria* strains and comprising an amino acid sequence as shown in SEQ ID NO: 8 or (ii) an antigenic fragment thereof; provided that the nucleic acid sequence is not SEQ ID NO: 74A or SEQ ID NO: 95A.

C<sub>3</sub>  
22. (New) The isolated nucleic acid according to claim 15, which encodes (i) a polypeptide specific for pathogenic *Neisseria* strains and comprising an amino acid sequence as shown in SEQ ID NO: 53 or (ii) an antigenic fragment thereof; provided that the nucleic acid sequence is not SEQ ID NO: 74A or SEQ ID NO: 95A.

23. (New) An expression vector comprising an expression cassette in which a nucleotide sequence as defined in claim 15 is placed under conditions allowing expression of said nucleotide sequence in a host cell.

24. (New) A host cell transformed with the expression vector according to claim 23.

---